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| 10/537,318 | 12/06/2005 | Mats Holmquist | 1209-0171PUS2 | 3205 |
| 2292 7590 04/13/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | | |
| EXAMINER XU, XIAOYUN | | | | |
| ART UNIT 1797 | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/537,318

Applicant(s)

HOLMQUIST ET AL.

Examiner

ROBERT XU

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 7-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed 03/30/2009 has been entered and fully considered. Claims 1-22 are pending, of which Claims 1 and 5 are amended, claims 20-22 are new.

Response to Amendment

2. In response to the amendment, the examiner maintains rejection over the prior art established in the previous Office action.

Election/Restrictions

3. Applicant's affirmed election with traverse of group I, Claims 1-6 in the reply filed on 03/30/2009 is acknowledged. The traversal is on the ground(s) that "there would be no undue burden on the Examiner to examine the two groups of the claims". This is not found persuasive because Group II, drawn to microfluidic device, has technical features, such as protrusion, volume metering unit, etc. that are not required in Group I. Additional search is needed for these features.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. **Claims 1-5, and 20-22** are rejected under 35 U.S.C. 102(e) as being anticipated by Clarke et al. (US 2002/0142470) (Clarke).

In regard to Claim 1, Clarke discloses a microfluidic arrangement in one of the embodiments (Figure 5). The arrangement comprises

A) microfluidic devices, each of which comprises a set (set I) of essentially equal microchannel structures that are comprised within a planar layer of the device (35 in Figure 5) (layer I) (see paragraph [0024], Figure 5),

each of said microchannel structures comprises an internal microconduit portion in which an active liquid flow is used (see paragraph [0024], Figure 5); and

B) an instrument for processing microfluidic devices, the instrument comprises a spinner motor and a rotary member (see paragraph [0024], Figure 5);

1) the rotary member comprises a group of one or more seats for holding microfluidic devices, each of the seats is capable of

- i) being positioned at the same radial distance as any of the other seats of the group (see paragraph [0024], Figure 5),
- ii) aligning layer I essentially radially at an angle α relative to the spin plane with $45^\circ < \alpha \leq 90^\circ$ (see paragraph [0024], lines 1-4, Figure 5).

II) the internal microconduit portion has an upstream part that can be positioned at a shorter radial distance than a downstream part when the corresponding microfluidic device is placed in any of the seats (see paragraph [0024], Figure 6).

In regard to Claim 2, Clarke discloses that the arrangement can rotate the micro device seat 180 degree in vertical plane (see paragraph [0024] lines 1-3 in page 4) and 360 degree in horizontal plane (see paragraph [0024], lines 5-6 in page 4). By using predetermined combination of independent rotational movements of both the rotation cog-ring 38 and the $\frac{3}{4}$ spheroid 36, the micro device 35 can be placed in any orientation relative to the g-vector 46 in three dimensions (see paragraph [0024] last 2 lines in page 4, and lines 1-7 in page 5). The combination of independent rotation also adjusts the seats in the radial and/or axial direction (see Figure 5).

In regard to Claim 3, Clarke discloses that the arrangement can hold the seats at a fix radial position (see paragraph [0024], Figure 5).

In regard to Claim 4, Clark discloses that the microfluidic device has two planar surfaces that are parallel to layer I and typically are rectangular with preference for each device being disc-shaped (see 35 in Figure 5).

In regard to Claim 5, the arrangement disclosed by Clarke can rotate the micro device seat 180 degree in vertical plane (see paragraph [0024] lines 1-3 in page 4).

In regard to Claim 20, Clarke discloses that the α can be essentially equal to 90° (see paragraph [0024], lines 1-4, Figure 5).

In regard to Claim 21, Clarke discloses that the rotary member comprises a group of one or more seats for holding at least one or more microfluidic devices (see Figure 5), each of the seats

i) is capable of being positioned at the same radial distance as any of the other seats of the group (see Figure 5),

ii) aligns layer I essentially radially at an angle α relative to the spin planes where $45^\circ < \alpha \leq 90^\circ$ (see paragraph [0024], lines 1-4, Figure 5), and

iii) is capable of positioning the corresponding positions in the microconduit portion of the microchannel structures in any of the microfluidic devices at essentially the same radial distance (see paragraph [0024], Figure 5).

In regard to Claim 22, Clarke discloses that the rotary member comprises at least four seats (see Figure 3).

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke in view of Sundberg et al. (US Patent 6,086,825) (Sundberg).

In regard to Claim 6, Clarke discloses a microfluidic device that comprises two essentially planar and parallel opposite sides and edge sides (see 35 in Figure 5, and 6), the microfluidic device has microchannel structure that has an inlet port IP present in an edge side (see Figure 6). Clarke does not specifically teach wettability of the inner walls of the inlet port that permits penetration by self-suction (capillarity) of a predetermined volume of an aqueous liquid. Sundberg discloses microfluidic chip that has fluidic introduction port that uses capillary force to retain the fluid within the port of defined size (see abstract). Sundberg teaches that the port can wick fluid from the surface of a pin, therefore, avoiding the need for complex pipette system (see Col.2, lines 40-52). At time of the invention it would have been obvious to a person of ordinary skill in the art to use a capillary inlet port as disclosed by Sundberg in Clarke's microfluidic chip, in order to avoid the need for complex pipette system.

Response to Arguments

8. Applicant's arguments filed 03/30/2009 have been fully considered but they are not persuasive.

Applicants argue that "the primary reference Clark U.S. '470 merely discloses a rotary member having an axis of rotation and an off-axis spherical ball, from which one quarter of a body of the ball is removed so as to provide a flat surface for holding a plate having channels. The ball may be rotated along two different axes so that the plate with channels can be orientated in any possible direction. A fluid flow is then induced in the channels by rotating the rotary member. Since the ball and the flat surface may be oriented in any direction, the Clark U.S. '470 reference fails to disclose or suggest the claimed angle as recited in claim 1 (i.e., $45^\circ < \alpha \leq 90^\circ$) and thus the rejection for anticipation has been overcome". Examiner believes that since the flat surface can rotate along two perpendicular axes, it is able to hold in a position in an angle α relative to the spin plane with $45^\circ < \alpha \leq 90^\circ$ as recited in Claims 1 and 21 or 90° as recited in Claim 20.

Applicants also argue that "the size of the spherical balls of Clark U.S. '470 are much larger than the plate held by the flat surface and there is a rotary member for rotating the balls". "Thus, according to the structure of Clark U.S.' 470, it is impossible to increase the number of microfluidic structure, which allows a plurality of sample to be processed simultaneously". Examiner believes that size and the shape of the rotating plate holder can be adjusted according to the number of microfluidic structures. For example, in one embodiment, Clark discloses 4 rotatable disc be held on the rotary member (see paragraph [0022], Figure 3).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT XU whose telephone number is (571)270-5560. The examiner can normally be reached on Mon-Thur 7:30am-5:00pm, Fri 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

4/8/2009

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

RX